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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/605,669 | 10/16/2003 | Wayne L. Ryan | SRCK:065<br>12642.0065.NPUS0 | 2668 |

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| EXAMINER | |
|---|---|
| BARNHART, LORA ELIZABETH | |
| **ART UNIT** | **PAPER NUMBER** |
| 1651 | |

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/605,669 | RYAN, WAYNE L. | |
| | Examiner | Art Unit | |
| | Lora E. Barnhart | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-27 are pending.

Claim 12 depends from claim 1. However, claim 1 is drawn to a method of making a collection tube comprising two specific components; claim 12 is drawn to "the method of claim 1, further comprising screening said collected and preserved cells using [one of various instruments]." It is not clear how these process-of-use steps depend from the process-of-making steps recited in claim 1. As such, claim 12 has been interpreted as being drawn to a method comprising collecting and preserving cells in a device made by claim 1 and screening said cells using one of various instruments.

Similarly, claim 25 depends from claim 14, which is a claim to a composition of matter. Claim 25, however, requires that the device of claim 14 be "used" along with one of various instruments. It is not clear how these process-of-use steps depend from the characteristics of the device recited in claim 14. As such, claim 25 has been interpreted as being drawn to a method comprising collecting and preserving cells in the device of claim 14 and screening said cells using one of various instruments.

See M.P.E.P. § 2173.05(p) for additional information on the examiner's interpretations of claims 12 and 25 and their dependent claims.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 14-~~28~~ 24, drawn to a collection device comprising a tube that contains an anticoagulant agent and a fixative agent and method of making the same, classified in class 435, subclass 307.1.

II. Claims 12, 13, 25, and 26, drawn to a method of screening cells comprising collecting and preserving cells in a device comprising a tube that contains an anticoagulant agent and a fixative agent and screening said cells using one of various instruments, classified in class 435, subclass 7.4.

III. Claim 27, drawn to a method for transporting cells for analysis comprising providing a device comprising a tube that contains an anticoagulant agent and a fixative agent, collecting cells in said tube, and transporting said tube, classified in class 435, subclass 374.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to Inventions II and III as product and multiple processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the device of Group I (which, according to claim 1, comprises a tube that contains an anticoagulant agent and a fixative agent) can be used for at least two different processes. The tube of Group I can be filled with cells and those cells can be screened in said tube, as in the method of Group II; alternatively, the tube of Group III can be filled with cells and used as a storage vessel. Because these inventions are distinct for the reasons given above, because they have acquired a separate status in the art as shown by their different classification, and because the literature search required for

Groups II and III is not required for Group I, restriction for examination purposes as indicated is proper.

Groups II and III are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group II is drawn to a method of screening cells within a device, while Group III is drawn to a method of storing and transporting cells. The methods do not require identical steps, and they do not have identical endpoints. Therefore, a search and examination of both methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Fixative agents: (a) diazolidinyl urea, (b) imidazolidinyl urea, (c) dimethoylol-5,5-dimethylhydantoin, (d) dimethylol urea, (e) 2-bromo-2-nitropropane-1,3-diol, (f) oxazolidines, (g) sodium hydroxymethyl glycinate, (h) 5-hydroxymethoxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, (i) 5-hydroxymethyl-1-1aza-3,7dioxabicyclo [3.3.0] octane, (j) 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3, 7dioxabicyclo [3.3.0] octane, and (k) quaternary adamantine, as in claims 1, 14, and 27.

Anticoagulants: (l) EDTA, (m) EGTA, (n) hirudin, (o) heparin, (p) citric acid, and (q) oxalic acid, as in claims 2 and 15.

Cells and cell samples: (r) epithelial cells, (s) bone marrow, (t) spinal fluid, and (u) abnormal tissue sample in a cellular suspension, as in claims 7 and 20.

Additional components: (v) an alcohol swab, (w) a gauze, (x) a tube holder, (y) a tourniquet, (z) a glove, (a') another cell collection tube, (b') a needle, (c') a lancet, (d') an adhesive strip, (e') a syringe, (f') a test strip, (g') a strip containing reagents for cell analysis, (h') a packaging means for storing said at least one component and said collection device to form a kit, and (i') a packaging means for transporting said collection device, as in claims 10 and 23.

Instruments: (j') a flow cytometer, (k') a hematology analyzer, (l') H3 by Bayer Corporation, (m') the Beckman Coulter STKS System, (n') the Beckman Coulter Gen-S System, (o') the Abbott Cell-Dyn 4000 Hematology System, (p') Bayer ADVIA 120 System, and (q') the Sysmex XE2100 System , as in claims 12 and 25.

Screening targets: (r') HIV, (s') HPV, (t') hepatitis, (u') leukemia, and (v') cancer, as in claims 13 and 26.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. That is, whether Group I, II, or III is elected, applicant should elect ONE fixative agent from (a)-(k), ONE anticoagulant from (l)-(q) above, and ONE cell or cell sample from (r)-(u) above. If Group I is elected, applicant should also elect ONE additional component from (v)-(i') above. If Group II is elected, applicant should also elect ONE instrument from (j')-(q') above and ONE screening target from (r')-(v') above. Currently, claims 1-27 are each generic to at least one set of species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Process claims that depend from or otherwise

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the protection against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Applicant should specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

LEB

IRENE MARX
PRIMARY EXAMINER